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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,820	01/28/2002	Jonathan S. Bogan	0399.2025-002	2441
21005	7590	11/06/2003	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,820	BOGAN ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following restriction requirement is directed to the set of claims and specification filed 1/28/02. Applicants' representative, Ms. Anne Collins, has confirmed that a later-filed specification and set of claims filed 10/4/02 are not part of the instant application (see the attached interview summary).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 25-31 and 54-57 drawn to a method of enriching an expression library comprising DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane, the expression library obtained, and methods of identifying a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane, classified in class 435, subclasses 6, 91.1, 325.
- II. Claims 22-24, 32-34, drawn to an isolated protein, classified in class 530, subclass 350.
- III. Claims 35-37, drawn to an antibody that specifically binds a particular protein, classified in class 530, subclass 387.1.
- IV. Claims 38-44, drawn to a method of identifying an agent that alters insulin stimulated GLUT4 trafficking at the plasma membrane, classified in class 435, subclass 29.
- V. Claims 45-46, drawn to a method for identifying an agent that binds to a protein comprising a UBX domain, classified in class 435, subclass 7.1.

- VI. Claims 47-49, drawn to a method of identifying an agent that alters the interaction between GLUT4 and L1, classified in class 435, subclass 5.
- VII. Claim 50, drawn to a method of altering insulin stimulated GLUT4 trafficking comprising contacting an insulin responsive cell with rapamycin, classified in class 435, subclass 375.
- VIII. Claim 51, drawn to a method of altering insulin stimulated GLUT4 trafficking comprising contacting a cell with an agent that binds to the UBX domain of a particular protein, classified in class 435, subclass 375.
- IX. Claim 52, drawn to a method of inhibiting GLUT4 externalization, classified in class 435, subclass 375.
- X. Claim 53, drawn to a method of enhancing GLUT4 externalization, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

Groups II-V and VIII are all directed to at least four distinct amino acid sequences (i.e. SEQ ID NOS: 1-4). As the structural/functional properties of these distinct polypeptide sequences are different from one another, and because the search of all four sequences together represents a search burden on the part of the Office, applicants are required to elect a single sequence from the four recited sequences if one of Groups II-V and VIII is elected. **This is not a species election.**

Inventions of Groups I, IV-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

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inventions of Groups I, IV-X are not disclosed as usable together and are biologically and functionally different and distinct from one another. The methods of Groups I, IV-X comprise steps that are not required for or present in the methods of the other groups: sorting cells containing an expression library comprising DNA encoding a protein involved in insulin stimulated GLUT4 trafficking (Group I), contacting test cells with an agent and measuring GLUT4 on the surface of the test cells as compared to suitable control cells (IV), contacting an isolated protein comprising an UBX domain with a test agent (V), combining GLUT4, L1 and a test agent in a mixture (VI), contacting an insulin responsive cell with rapamycin (VII), contacting a cell with an agent that binds to the UBX domain of a particular protein (VIII), contacting a cell comprising GLUT4/L1 complexes with an agent that inhibits disassociation of the complex (IX), and contacting a cell comprising GLUT4/L1 complexes with an agent that enhances disassociation of the complex (X). The end results of the different methods are different: enrichment of an expression library for cells encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane and/or isolation of the protein (Group I), identification of an agent that alters insulin stimulated GLUT4 trafficking at the plasma membrane (Group IV), identification of an agent that binds an isolated protein comprising an UBX domain (Group V), identification of an agent that alters the interaction between GLUT4 and L1 (Group VI), alteration of insulin stimulated GLUT4 trafficking via the use of rapamycin (Group VII), alteration of GLUT4 trafficking comprising contacting a cell with an agent that binds the UBX domain of specific proteins (Group VIII), inhibition of GLUT4 externalization (Group IX) and enhancement of GLUT4 externalization (Group X). Thus, the operation, function and effects of the different methods are different and distinct from each other.

Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Inventions of Group II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, functions and effects. For example, the isolated protein of Group II is normally involved in GLUT4 trafficking whereas the protein of Group III is an antibody that functions by binding specific epitopes within a given protein.

Inventions of Group II and Groups I, III-IV and VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the protein of Group II is not required for or present in the methods and/or compositions of the other Groups. For example, the methods of Group I are not required for producing the protein of Group II, which can be made synthetically.

Inventions of Group II and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated protein can be used to generate an antibody against the protein or for functional/structural characterization.

Inventions of Group III and Groups IV-VI and VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Group III can be used in the methods of each of Groups IV-VI and VIII. Alternatively, the antibodies can be used in methods of determining expression of the cognate proteins in different cell samples.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product

and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. In addition, the literature search required for each of the different groups is not coextensive with the search required for examination of any of the other groups (e.g. inhibitors of GLUT4 externalization versus enhancers of GLUT4 externalization).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

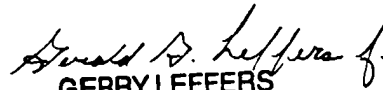
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

Ggl


GERRY LEFFERS
PRIMARY EXAMINER